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Re: NMFS Chlorpyrifos, Diazinon, and Malathion Biological Opinion

Dear Ms. Perry and Colleagues:

We are writing on behalf of our clients Dow AgroSciences LLC, Makhteshim Agan of North America, Inc., d/b/a ADAMA, and FMC Corporation (collectively, the "OP Registrants"), to provide joint comments on certain legal issues raised by the National Marine Fisheries Service's ("NMFS's") December 29, 2017 Biological Opinion on the Environmental Protection Agency's Registration of Pesticides containing Chlorpyrifos, Diazinon, and Malathion ("the BiOp"). Our clients and their affiliates hold EPA registrations for products containing one or more of the three organophosphate ("OP") active ingredients that are the subject of the BiOp. The issues summarized here, in the attachments to this letter, and in the individual comments being provided by each company require that EPA set aside the BiOp and reject its Reasonable and Prudent Alternatives ("RPAs") and Reasonable and Prudent Measures ("RPMs") because those recommendations are unsupported and unlawful.

Introduction

Once EPA initiated consultation with NMFS regarding the potential impacts of registration of OP pesticides, NMFS had a statutory obligation to rely on the "best scientific and commercial data available" in providing EPA with advice and recommendations.[1] The BiOp should present sound scientific analysis based on information that meets that standard, but it does not.

As explained in the first attachment to this letter, a report by the consulting firms Intrinsik and Stone Environmental, there are serious scientific and technical

[1] ESA § 7(a)(2), 16 U.S.C. § 1536(a)(2).

deficiencies in NMFS's BiOp. In part, these are due to deficiencies in the Biological Evaluations ("BEs") EPA provided NMFS for the OP pesticides in January 2017. The inadequacy of NMFS's effort is further documented in the reports being submitted by each of the OP registrants individually, in comments filed by our clients and many others on the drafts of the BEs that EPA made available in April of 2016 that appear in www.regulations.gov dockets;[2] and in the second attachment to this letter and the reports accompanying it. That attachment includes letters that were sent to former EPA Administrator Pruitt and Commerce Secretary Wilbur Ross, with copies to many other involved governmental personnel protesting and documenting the inadequacy of the BEs.

Our clients do not know whether EPA transmitted their comments on the draft BEs to NMFS when the Agency submitted "final" versions of the BEs. Our clients are aware, however—both by virtue of the analysis included in the second attachment to this letter and EPA's explanation of its incomplete response to those comments—that many of the comments were ignored by EPA.[3] And, as documented in the Intrinsik-Stone Report (Attachment 1), the comments also were not addressed by NMFS.

We further explain the legal basis for the conclusion that the BiOp is fatally flawed and was unlawfully issued (beginning at page 3). We then address (beginning at page 13) EPA's legal obligations in the face of these failings. Finally, we address (beginning at page 15) a key lesson of the production of the BiOp: that it is time to reconsider the approaches to meeting the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Endangered Species Act (ESA) obligations of EPA and the Services that were set forth in the 2013 document published by EPA, the Fish and Wildlife Service (FWS), NMFS, and the Department of Agriculture (USDA) entitled Interim Approaches for National-Level Pesticide Endangered Species Act Assessments Based on the Recommendations of the National Academy of Sciences April 2013 Report (the "Interim Approaches Report").[4]

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[2] *See* EPA-HQ-OPP-2016-0167 (Notice of Availability); EPA-HQ-OPP-2009-0317 (Malathion); EPA-HQ-OPP-2008-0351 (Diazinon); EPA-HQ-OPP-2008-0850 (Chlorpyrifos).

[3] EPA, Response to Comments on the Draft Biological Evaluations for Chlorpyrifos, Diazinon, and Malathion at 2 (Jan. 2017) ["hereinafter EPA Response to Comments"], https://www3.epa.gov/pesticides/nas/final/response-to-comments.pdf.

[4] EPA, Interim Approaches for National-Level Pesticide Endangered Species Act Assessments Based on the Recommendations of the National Academy of Sciences April 2013 Report (Oct. 2015) [hereinafter "Interim Approaches Report"], https://www.epa.gov/sites/production/files/2015-07/documents/interagency.pdf.

I. The BiOp Was Issued in Violation of the ESA, the Services' Regulations, Relevant Policy Documents, and the Decision of the U.S. Court of Appeals for the Fourth Circuit on Its Prior Version.

A. NMFS Was Legally Obliged to Look Beyond the Information Presented to It in the BEs, But Did Not.

The BEs that EPA sent to NFMS in support of its consultation request were sorely deficient. This is supported by the Intrinsik-Stone General Comments (Attachment 1), the individual active ingredient reports being submitted today by each registrant, and the attachments to the registrants' letters to the EPA Administrator and Secretary of Commerce (Attachment 2).

As the General Comments report summarizes, "[f]or quantitative risk characterization, the BiOp relied almost, if not entirely, on the exposure estimates and effects metrics from the EPA's BEs, many of which were incorrect."[5] The BiOp also omitted valuable data that demonstrated that actual application of products containing the OP active ingredients is far lower than what the BiOp assumed, a considerable amount of relevant surface water monitoring data, and data related to several other important lines of evidence, such as field studies and incident reports.[6] As the report concluded:

> NMFS did not provide crucial data and information on the input parameters selected, made numerous arbitrary decisions on factors that may or may not affect NMFS listed species, did not look for potential positive influences for some of these parameters, and in the end applied, subjective professional judgement in such an opaque manner that the reader cannot follow or duplicate the results reported.[7]

NMFS thus failed to meet its most fundamental statutory obligation in consultation: to ground its opinion in the "best scientific and commercial data available."[8] A biological opinion that ignores available relevant information is unlawfully arbitrary and capricious.[9] NMFS's excuses that pertinent data is not

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[5] Intrinsik-Stone General Comments at 5.

[6] *Id.* at 5–8.

[7] *Id.* at 92.

[8] 16 U.S.C. § 1536(a)(2).

[9] *See, e.g., Conner v. Burford*, 848 F.2d 1441, 1454 (9th Cir. 1988). It would be no defense for NMFS to argue that it only needed to consider information EPA provided in the BEs. NMFS's duty to consider "available" commercial and scientific information is broader; it must consider any

available "at a useful scale," is "based on limited geographic sampling," and/or is "variable over time" are wholly insufficient.[10] Caselaw makes clear that "incomplete information . . . does not excuse the failure to comply with the statutory requirement of a comprehensive biological opinion using the best information available."[11] The BiOp here has failed to meet this basic statutory obligation.

B. One of NMFS's Most Glaring Failures Was to Not Consider Information on Actual Product Usage and Historical Effects.

NMFS's analysis assumed that all products manufactured from the insecticidal active ingredients will be used at "the highest labeled rate for the use site or crop grouping (EECs)."[12] NMFS did not consider usage data from the past half-century to test the appropriateness of that assumption.[13] As a result, the effects of the hypothetical action that NMFS analyzed bear no resemblance to the effects that are reasonably certain to occur from the actual reregistration, and are a legally indefensible basis for NMFS's analysis.

Section 7 of the ESA requires that action agencies consult with the Services as necessary to ensure that their actions are "not likely to jeopardize" listed species or adversely modify critical habitat.[14] Under the Services' regulations, determining whether an action is likely to do so requires an evaluation of both "direct" and "indirect" effects.[15] The regulations do not define "direct effects," but do state that "indirect effects" are those that "are caused by the proposed action but occur later in time, but still are *reasonably certain to occur*."[16] (emphasis added).

EPA's grant of a registration for a pesticide product or approval of reregistration has only indirect effects, because the grant or approval merely allows

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information provided by the action agency "or otherwise available." *Ctr. for Biological Diversity v. BLM*, 698 F.3d 1101, 1120 (9th Cir. 2012) (quoting 50 C.F.R. § 402.14(g)(1)).

[10] *See* BiOp at 11-36 (explaining that usage data would not be considered, without citation to or discussion of any specific data, because NMFS perceived it to).

[11] *Conner*, 848 F.2d at 1454; *see also Ctr. for Biological Diversity v. Salazar*, 804 F. Supp. 2d 987, 1008 (D. Ariz. 2011) (rejecting FWS's assertion that the effects of climate change were "too uncertain" to consider in the BiOp).

[12] BiOp at 11-34.

[13] Chlorpyrifos was first registered for use in 1965. Diazinon and malathion were first registered for use in 1956.

[14] 16 U.S.C. § 1536.

[15] 50 C.F.R. § 402.02.

[16] *Id.* (under definition for "effect of the action").

the distribution, sale, and use of the product in specified ways (often tens or hundreds of specified ways). All exposures to the product and its constituents are caused later, when the products are used by a grower or other entity who has purchased them (often through independent distributors). The environmental exposures that arise from usage are therefore, by definition, indirect effects of product registration. Those exposures must be evaluated only after consideration of whether they are "reasonably certain" to occur in a particular area or at a particular concentration. [17]

This is a critically important point, because the insecticide products of concern here are generally not used at the greatest rates permitted by EPA—what are referred to as "maximum label rates." This is most fundamentally due to the fact, as EPA is well aware, that the actual usage depends on the pest a farmer or public health organization is seeking to control, the intensity of the infestation, and application methods and conditions. Indeed, labels typically specify ranges of application rates or methods. Thus, labels are properly seen as establishing *permitted* maximum usage rates, but *not mandating* them.

Products containing the three insecticides at issue here have been in use for over 50 years. During that period, crops on which they may be applied, other uses to which they may be put, and allowable usages and maximum label rates have been dramatically decreased. A considerable amount of data has been collected that documents actual usage and, for that matter, the environmental effect of that usage on the species over which NMFS has jurisdiction. In order to properly assess how the three OP pesticides affect listed species, NMFS should evaluate actual historic use rates and the actual locations in which the products are used, not merely the maximum possible rates and possible locations.

Conclusions about the impact of reregistration also must consider historical use to allow proper assessment of the likely effects of the action. The "effects of the action" which the Service must consider are those which "will be added to the

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[17] By contrast, direct effects on listed species from an agency action could come from federal construction and operation of hydroelectric projects, operation of a fish hatchery, or construction of roads on federal land—where the federal agency's action is itself causing direct changes to the physical natural environment.

Analogously, in *Fla. Key Deer v. Paulison*, 522 F.3d 1133 (11th Cir. 2008), FWS had concluded that the National Flood Insurance Program was indirect cause of greater development in Florida Keys. The Court found that the program was subject to ESA consultation because FEMA had the authority "to prevent the indirect effects" of the program. Similarly, in *Ctr. for Biological Diversity v. U.S. Dep't of Hous. & Urban Dev.*, 541 F. Supp. 2d 1091, 1100 (D. Ariz. 2008), *aff'd*, 359 F. App'x 781 (9th Cir. 2009), the plaintiff argued that any development that resulted from use of the HUD loan guarantees would be an indirect effect. The court agreed that such development theoretically might require consultation, although it ultimately found consultation unnecessary because of HUD's limited discretion over the program.

environmental baseline."[18] The baseline includes, among other things, past and present impacts of federal and private actions. In other words, the analysis focuses on whether the reregistration, in the context of the historical use and effects, will cause jeopardy to any species.

As the Ninth Circuit has stated, to "jeopardize" requires causation, i.e., an exposure to "some new risk of harm."[19] In the absence of a good reason to believe that use will increase from historical levels after reregistration (which is not the case here, and has not been suggested by any stakeholders), consideration of the actual effects produced by historical use is central to understanding the likely effects of reregistration on listed species.

Any analysis proceeding from a hypothetical baseline will be meaningless. In *National Wildlife Federation v. NMFS*, a NMFS BiOp was declared arbitrary and capricious because it attempted to use a hypothetical "reference operation" as the environmental baseline instead of the actual conditions in the relevant river.[20] NMFS's failure to consider actual conditions caused it to "conduct . . . its jeopardy analysis in a vacuum."[21]

In the OP BiOp, NMFS failed to consider species' population histories over the past fifty-plus years as a line of evidence with respect to likely effects. This was an error of law. Historical effects are relevant because the OP pesticides have been used for the past fifty-plus years subject to registrations that, in many cases, permitted use in higher concentrations than the current registration.

One example of an error caused by considering effects on a species "in a vacuum" without reference to historical usage and the species' history is the Louisiana Black Bear. EPA's draft BEs, released for comment on April 11, 2016, predicted that reregistering chlorpyrifos (without adding any new authorized uses) was "likely to adversely affect" the bear. The analysis included "high risk/high confidence" findings for mortality, growth, behavior, and indirect effects to prey.[22]

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[18] 50 C.F.R. § 402.02.

[19] *Nat'l Wildlife Fed'n v. NMFS*, 524 F.3d 917, 930 (9th Cir. 2008).

[20] *Id.* at 926.

[21] *Id.* at 929. Attempting to compare hypothetical effects to an actual baseline is equally problematic. In *Swan View Coal. v. Barbouletos*, No. cv 06–73–M–DWM, 2008 WL 5682094 (D. Mont. June 13, 2008), *aff'd on other grounds* 348 F. App'x 295 (9th Cir. 2009), FWS's BiOp compared actual (illegal) historical use to hypothetical (legal) future use. By doing so, FWS was able to paradoxically conclude that despite USFS's proposal to *increase* the legally allowable amount of snowmobiling in a National Forest, actual levels would *decrease*. The court rejected this attempt to compare actual and hypothetical use. *Id.* at *1.

[22] EPA Draft BE for Chlorpyrifos, Appendix 4-3e.

One month earlier, however, and notwithstanding a half-century of use of chlorpyrifos and possible resulting exposures, FWS had declared that the bear was no longer threatened.[23]

Finally, the BiOp is flawed because it fails to account for species noted as having stable or increasing abundance. Historical effects on listed populations (alongside an assessment of other factors that have affected the environmental baseline) can provide powerful evidence about the actual effects which result from a particular product's registration or reregistration. In the context of products that have been registered for more than fifty years, jeopardy calls can only be made rationally after reviewing data on historical usage and effects.

C. NMFS Failed to Properly Involve Registrants and Other Stakeholders in Preparing the BiOp and Developing RPAs.

Where a proposed agency action under ESA consultation is the issuance of a permit or license to an "applicant," ESA section 7(b) and the Services' regulations summarized immediately below require that NMFS involve the applicant in the consultation process.[24] Entities to which EPA has issued pesticide registrations, such as the holders of registrations for products containing OP pesticides, are "applicants" for purposes of the ESA.[25] However, NMFS wholly ignored this obligation in preparing the BiOp.

NMFS's consultation implementing regulations, 50 C.F.R. Part 402, Subpart B, implement ESA section 7(b) by requiring that NMFS discuss with applicants in the course of consultation the Service's review of "all relevant information provided by the [action] agency or otherwise available,"[26] the Service's evaluation of "the current status of the listed species or critical habitat"[27] and "the effects of the action and cumulative effects on the listed species or critical habitat,"[28] and "the basis for any finding in the biological opinion, and the availability of reasonable and prudent alternatives (if a jeopardy opinion is to be issued) that the agency and the applicant

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[23] 81 Fed. Reg. 13,124 (Mar. 11, 2016) (noting that "the threats have been eliminated or reduced, adequate regulatory mechanisms exist, and populations are stable such that the species is not currently, and is not likely to again become, a threatened species within the foreseeable future").

[24] 16 U.S.C. § 1536(b) (providing various forms of engagement for applicants).

[25] *See* EPA, Enhancing Stakeholder Input in the Pesticide Registration Review and ESA Consultation Processes and Development of Economically and Technologically Feasible Reasonable and Prudent Alternatives at 9 (Mar. 27, 2013) [hereinafter "Enhancing Stakeholder Input Report"].

[26] 50 C.F.R. § 402.14(g)(1) (required by § 402.14(g)(5)).

[27] *Id.* § 402.14(g)(2).

[28] *Id.* § 402.14(g)(3).

can take to avoid violation of section 7(a)(2)."[29] But no discussions covering these topics took place between the OP pesticide registrants and NMFS.[30]

The Services' core regulations also require NMFS to "utilize the expertise" of applicants in identifying RPAs.[31] OP pesticide registrants have ample expertise that would have aided NMFS if it had followed this procedure. Instead, NMFS ignored it.

In addition, NMFS is to provide a copy of its draft BiOp to the applicant upon request, so that the applicant may send comments directly to the Service.[32] NMFS did not provide registrants with any draft of the BiOp.

The NMFS also failed to comply with its supplemental "counterpart" regulations that address FIFRA consultations. These and provide "additional means to satisfy [consultation] requirements . . . for certain regulatory actions under FIFRA."[33] Those regulations "closely follow the procedural steps" and "combine the central concepts and processes" of the formal consultation process.[34] Among other things, for example, they allow applicants to obtain, review, and comment upon the Service's draft biological opinion and require NMFS to "discuss with . . . the applicant the Service's review and application and the basis for its findings."[35]

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[29] *Id.* § 402.14(g)(5)

[30] EPA is of course aware of NMFS's failure to involve the applicants. The Federal Register notice to which these comments respond noted that "NMFS issued the final BiOp without having received input from the public and applicants (pesticide registrants)." 83 Fed. Reg. 12,754, 12,755 (Mar. 23, 2018).

[31] *Id.*

[32] *Id.*

[33] 50 C.F.R. § 401.41; *see generally* 50 C.F.R. Part 402, Subpart D.

[34] 69 Fed. Reg. 47738 (Aug. 5, 2004) (preamble to promulgation of regulations).

[35] 50 C.F.R. § 402.46(c)(2). If this language were not clear enough, NMFS confirmed the requirements in the preamble that accompanied the Services' rulemaking implementing 1982 amendments to the ESA. NMFS also noted that those regulation amendments served to "provide an opportunity for permit or license applicant involvement in *all phases* of the consultation procedures . . . . Clearly, the permit or license applicant plays an *active role* in the consultation process." Interagency Cooperation—Endangered Species Act of 1973, as Amended; Final Rule, 51 Fed. Reg. 19926-01, 19926–27 (June 3, 1986) (emphasis added). The Services specifically cited the House Conference Committee Report on the 1982 Amendments, which stated that "it is the clear intention of the Committee that the applicant should be involved in *every aspect* of the consultation process." H.R. Conf. Rep. No. 97-835, at 26. (1982) (emphasis added).

As the Services' Consultation Handbook further explains, "the applicant is entitled to review draft biological opinions obtained through the action agency, and to provide comments . . . ."[36] NMFS did none of these things.

NMFS, in some cases along with EPA, also has issued guidance reinforcing the requirements of the regulations. For example, the Consultation Handbook confirms that the Services must "discuss the basis of their biological determination with the applicant and seek the applicant's expertise in identifying reasonable and prudent alternatives to the action if likely jeopardy or adverse modification of critical habitat is determined."[37] Similarly, the Enhancing Stakeholder Input Report states that NMFS will "convene a meeting with EPA and the applicant" after initiation of consultation "to identify what additional information . . . can be provided to develop the draft biological opinion."[38] These things did not happen.

NMFS included in the BiOp a section captioned "Consultation History."[39] It describes only a series of meetings held by NMFS and other agencies between August 2013 and December 2016 to develop policies to be reflected in all pesticide biological opinions, many of which involved only governmental employees. Nothing could more clearly demonstrate NMFS' failure to comply with its obligations with the OP registrants. NMFS never contacted any of the Plaintiffs, let alone had a discussion with them regarding the BEs or NMFS's review and evaluation of them, even though Plaintiffs submitted detailed comments and analyses to NMFS regarding the shortcomings of the BEs.

D. The BiOp was Issued Without Compliance with a Direct Ruling of the Fourth Circuit.

As explained in its introductory section, the 2017 BiOp replaced and expanded upon a 2008 version of a similar document (the "2008 BiOp") that evaluated only impacts of the active ingredients at issue on salmonids.[40] The 2008

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[36] FWS & NMFS, Endangered Species Consultation Handbook at 2-13 (Mar. 1998) [hereinafter "Consultation Handbook"], https://www.fws.gov/endangered/esa-library/pdf/esa_section7_handbook.pdf.

[37] Consultation Handbook at 2-13.

[38] Enhancing Stakeholder Input Report at 8. Similarly, in its 2014 Report to Congress on its efforts to address the ESA/FIFRA issues NMFS committed to "maintaining a robust dialogue with all of our stakeholders to ensure transparency throughout the pesticide consultation process." EPA, FWS, NMFS, and USDA, Interim Report to Congress on Endangered Species Act Implementation in Pesticide Evaluation Programs at 23 (Nov. 2014), https://www.epa.gov/sites/production/files/2015-07/documents/esareporttocongress.pdf.

[39] BiOp at 2-4 to 2-11.

[40] BiOp at 1-2.

BiOp was vacated by the Fourth Circuit in 2013 because it "was not the product of reasoned decision-making" but instead "relied on a selection of data, tests, and standards that did not always appear to be logical, obvious, or even rational."[41] The appellate court thus directed the BiOp's remand to NMFS for a "renewed agency process."[42]

The Court of Appeals decision analyzed in detail three of NMFS's errors in the 2008 BiOp and directed that they be corrected on remand:

- the assumption that all subyearling juvenile salmonids in the wild are exposed for 96 straight hours to lethal concentrations of the OPs,
- reliance on outdated water-monitoring data, and
- the prescribed used of uniform crop buffers to protect water bodies, regardless of the water body's size or flow.[43]

The Court of Appeals also directed that the revised biological opinion address "not only the flaws we identified but also any additional matters that may be raised on remand,"[44] and ordered NMFS to undertake a "renewed agency process" to develop future biological opinions in a manner "consistent with [its] opinion."[45]

Unfortunately, the 2017 BiOp did not correct these flaws. As explained in the Intrinsik-Stone Report (Attachment 1):

- NMFS once again failed to justify or explain the assumption of 96 hours of continuous, lethal levels of pesticides to salmon. To compound matters, NMFS used flawed EECs and no information from targeted monitoring studies. NMFS also did not account for the expected variation in concentrations between and within different ESUs and DPSs, instead using the same exposure values for all population models.
- Although NMFS did not use out-of-date monitoring data, as was the case in the 2008 BiOp, the reality is that it did not use monitoring data in any of the risk analyses in the 2017 BiOp that we could find.

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[41] *Dow AgroSciences LLC v. NMFS,* 707 F.3d 462, 464, 475 (4th Cir. 2013).

[42] *Id.* at 475

[43] *Id.* at 470–475.

[44] *Id.*

[45] *Id.*

- The sizes of the RPA buffers are somewhat flexible depending on which mitigation measures are adopted under the proposed point system. That said, there is insufficient flexibility to achieve similar reductions in exposure and risk for a small backwater habitat versus the main channel of a large river. In the 2017 BiOp, NMFS relied on AgDrift Tier 1 modeling to determine buffer sizes that would reduce drift by 99%. However, there were no supporting analyses to determine the exposure reductions expected with vegetative buffer strips and other RPA elements. As in the 2008 BiOp, no scientific analyses were conducted to determine how protective the RPA elements would be.[46]

Intrinsik-Stone then continued:

> As we have detailed above and elsewhere, the exposure and effects analyses conducted by EPA in the preceding BEs (EPA, 2016a-c, 2017a-c) and the risk characterization and population modeling conducted by NMFS in the 2017 BiOp were highly flawed. There was no weight of evidence assessment, but rather the same line of evidence (comparison of highly conservative modeled exposure values to sensitive lab-based effects metrics) was parsed in many different ways. Finally, it was clear that NMFS did not wish to conduct ESU- and DPS-specific analyses and instead relied on generic exposure modeling results and made up exposure values in the population models to characterize risk.[47]

II. In the Face of NMFS's Failures, EPA Has No Obligation to Accept the BiOp or to Adopt Its RPAs.

The commenting registrants are challenging the BiOp based on NMFS's failings in a pending lawsuit.[48] But no decision in that proceeding is likely before early next year. Even before that decision, however, EPA has no obligation to adopt the BiOp's RPAs or RPMs because of the substantive and procedural defects in the BiOp.

NMFS failed to comply with its regulations and established procedures to involve the registrants (and other stakeholders) in the development of the BiOp and its RPAs. NMFS's violation of those requirements renders the BiOp arbitrary and capricious under the Administrative Procedure Act and without legally binding

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[46] Intrinsik-Stone Report at 51.

[47] *Id.*

[48] *Makhteshim Agan of N. America v. NMFS*, No. 18-cv-961 (D. Md.).

significance.[49] The inadequacies of NMFS's information gathering and analysis relieve EPA of any obligation to accept the BiOp as valid or to adopt the RPAs or RPMs.

A. EPA Should Reject the Patently Defective BiOp.

EPA must independently assess the substantive and procedural aspects of the BiOp. "The ultimate responsibility for determining whether section 7 of the ESA has been satisfied rests with the federal agency that was engaged in consultation."[50] And it is a fundamental principle of administrative law that an agency "must scrupulously observe rules, regulations, or procedures which it has established."[51]

An action agency cannot lawfully rely on a defective biological opinion, particularly when the action agency knows the BiOp is "bereft of key data."[52] Indeed, if EPA were to rely upon this flawed BiOp, EPA's action would be subject to successful legal challenge.[53] Consultation with NMFS satisfies EPA's procedural obligations under the ESA, but EPA may not rely solely on the BiOp to establish conclusively its compliance with its substantive obligations under section 7(a)(2), otherwise adoption of RPAs in the BiOp is arbitrary and capricious.[54]

NMFS's failure to comply with applicable procedural requirements makes the BiOp itself unlawful and unenforceable. The procedures described in the Enhancing Stakeholder Input Report and Consultation Handbook are binding on NMFS insofar as they clearly establish procedures comparable to the Services'

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[49] *Bennett v. Spear*, 520 U.S. 154, 175 (1997); *Dow AgroSciences LLC v. NMFS*, 637 F.3d 259, 267; *Sierra Club v. U.S. Army Corp. of Eng'rs*, 295 F.3d 1209, 1216 (11th Cir. 2002).

[50] *Fla. Key Deer v. Brown*, 364 F. Supp. 2d 1345, 1358 (S.D. Fla. 2005) (citing *Natural Resources Defense Council v. Army Corp. of Engineers,* No. 99-2899-civ, 2001 WL 1491580, at *6 (S.D. Fla. June 28, 2001)), *aff'd sub nom. Fla. Key Deer v. Paulison*, 522 F.3d 1133 (11th Cir. 2008).

[51] *See United States v. Heffner*, 420 F.2d 809 (4th Cir. 1969) (internal quotations and citations omitted).

[52] *Colorado Envtl. Coal. v. Office of Legacy Mgmt.*, 302 F. Supp. 3d 1251, 1274 (D. Colo. 2018).

[53] *Pyramid Lake Paiute Tribe of Indians v. U.S. Dep't of Navy*, 898 F.2d 1410, 1415 (9th Cir. 1990); *see also Pub. Employees for Envtl. Responsibility v. Hopper*, 827 F.3d 1077, 1090 (D.C. Cir. 2016) (finding NMFS's conclusions arbitrary for failure to consider evidence provided by plaintiff during earlier phase of litigation); *Intertribal Sinkyone Wilderness Council v. NMFS*, 970 F. Supp. 2d 988, 1001 (N.D. Cal. 2013) (finding NMFS BiOp arbitrary for failure to consider published studies which were not part of the record).

[54] *Pyramid Lake*, 898 F.2d at 1415 (citing *Stop H–3 Ass'n v. Dole*, 740 F.2d 1442, 1459–60 (9th Cir.1984), *cert. denied*, 471 U.S. 1108 (1985)).

formal regulations.[55] And the fact that NMFS failed to follow those procedures means that EPA must ultimately reject the BiOp.

B. EPA Should Reject the RPAs and RPMs as Invalid.

It would arbitrary and capricious for EPA to adopt and implement the BiOp's RPAs and RPMs that were developed in violation of the ESA and related regulations and that violated the Fourth Circuit's order. EPA must assess the validity of RPAs, especially to determine if they are economically and technically feasible.[56] EPA makes an independent determination as to the validity of RPAs.[57] "A 'reasonable and prudent alternative' is a flexible standard for the consulting agency."[58]

EPA is not required to adopt RPAs or RPMs that are contrary to law. The consulting agency "need only have adopted a final RPA [formulated by FWS] which complied with the jeopardy standard and which could be implemented by the agency."[59] The OP registrants have serious concerns that the RPAs will not comply with the jeopardy standard because of the clearly erroneous elements of the BiOp, including the failure to engage with registrants or to comply with the Fourth Circuit order. And, as explained in the comments, the RPAs are not technically and economically feasible, which is a requirement for valid RPAs. EPA is not obligated to adopt the RPAs because they cannot be implemented.

Where the action agency takes adequate steps to comply with the ESA, it may reject RPAs.[60] It is entirely appropriate for an action agency to dispute the basis or effects of RPAs if it has a valid basis for doing so.[61] And Courts have found that an action agency may proceed with their action despite a jeopardy

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[55] *See Gen. Elec. Co. v. EPA*, 290 F.3d 377, 383 (D.C. Cir. 2002) (stating that a guidance document issued by EPA "on its face . . . imposes binding obligations upon . . . the Agency," and holding that "it has the force of law").

[56] 50 C.F.R. § 402.02 (defining RPAs as "economically and technologically feasible" alternative actions).

[57] *See Dow AgroSciences LLC*,707 F.3d at 466 (discussing revision to draft BiOp following EPA comments).

[58] *San Luis & Delta-Mendota Water Auth. v. Jewell*, 747 F.3d 581, 624 (9th Cir. 2014) (discussing wide-range of consulting agency discretion in response to proposed RPAs).

[59] *Sw. Ctr. for Biological Diversity v. U.S. Bureau of Reclamation*, 143 F.3d 515, 523 (9th Cir. 1998).

[60] *Tribal Vill. of Akutan v. Hodel*, 869 F.2d 1185, 1194 (9th Cir. 1988) (finding that rejection of some of NMFS's RPAs was not arbitrary and capricious).

[61] *See, e.g., Ideker Farms, Inc. v. United States*, 136 Fed. Cl. 654, 666 (2018) (describing Corps' objections to RPAs and subsequent revision by FWS).

finding and proposed RPAs where the action agency has concluded that doing so would not violate the ESA.[62] Based on this authority, the numerous flaws taken by this BiOp in developing the RPAs and RPMs require EPA to set them aside.

III. The Interim Approaches Should be Abandoned Based on the Experience of Preparing the BiOp.

The BiOp and the BEs that preceded it purportedly were prepared in accordance with the Interim Approaches to FIFRA-ESA issues adopted by the agencies in November 2013.[63] Our clients have believed from the start that the Interim Approaches were fundamentally flawed. The production of the BEs and the BiOp confirms that view in spectacular fashion.[64]

As demonstrated above, in failing to "explain or support several assumptions critical to its conclusions," both NMFS and EPA violated the Fourth Circuit's direction that an agency acting to implement the ESA must explain its analysis "with sufficient clarity" to allow stakeholders to determine whether the analysis is "the product of reasoned decisionmaking."[65]

In the Interim Approaches Report released by EPA, the Services, and USDA in November 2013, and in various accompanying and subsequent statements, the agencies have made clear that they anticipated the interim process to be iterative. For example, the Interim Approaches document itself stated the "[t]he Agencies will work together to develop refined and improved techniques and approaches over time."[66] The National Research Council's 2013 report similarly made clear that the process should be informed by ongoing, practical experience.[67]

Those iterative efforts clearly were intended to be informed by the Enhancing Stakeholder Input Report published on behalf of all the agencies by EPA earlier in 2013, and by the requirements of the Services ESA consultation

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[62] *Kandra v. United States*, 145 F. Supp. 2d 1192, 1200 (D. Or. 2001) (citing *Pac. Coast Fed'n of Fishermen's Ass'ns v. U.S. Bureau of Reclamation*, No. 00-cv-1955 (N.D. Cal. April 16, 2001)).

[63] Interim Approaches Report, *supra* note 4.

[64] The deficiencies of the BEs were documented in Attachment 2, the comments to EPA that preceded them. The deficiencies of the BiOp itself are documented in Attachment 1 and the individual comments being filed in the current docket.

[65] *Dow AgroSciences LLC*, 707 F.3d at 464, 475.

[66] Interim Approaches Report at 1.

[67] National Research Council, Assessing the Risk to Endangered and Threated Species from Pesticides (2013), http://www.nap.edu/catalog.php?record_id=18344.

regulations, reviewed above, that mandate the involvement of the OP registrants in the production of this BiOp.[68]

Moreover, Congress and the President endorsed the concept that the Interim Approaches were to be considered an iterative process in February 2014, with the enactment of section 10013 of the Agricultural Act of 2014.[69] That provision required submission to Congress of two reports on implementation of the NRC's 2013 recommendations and efforts by EPA and the Services to minimize delays in integrating the requirements of sections 3 and 33 of FIFRA (which relate to pesticide registration and establish deadlines for action on registration actions) and the consultation requirements of section 7 of the ESA.

As the Conference Report on section 10013 stated:

> It is the Managers [*sic*] intent through routine oversight to keep all involved government entities focused on promptly building the "Interim Plan" into a final set of processes and procedures that will maximize the efficient use of limited governmental resources, minimize delays in registrations actions under Section 3 and 33 of FIFRA, make it possible for EPA to comply with the FIFRA requirement that all registrations be reviewed every fifteen years, and ensure meaningful public participation. Additionally, the Managers through this provision reemphasize Congress's intention that all reasonable and prudent alternatives to address ESA concerns are economically and technologically feasible.[70]

EPA and the Services (along with USDA) also acknowledged the importance of learning through the interim process, and modifying strategies accordingly, in the November 2014 report to Congress required by section 10013.[71] Among other important commitments, that report stated that "EPA, FWS, and NMFS will apply the interim measures to initial consultations and, based upon the experience gained with these approaches as well as any new science that may develop, modify procedures as appropriate."[72]

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[68] *See, e.g.*, 50 C.F.R. §§ 402.10(c), 402.11, 402.14(d).

[69] Agricultural Act of 2014, Pub. L. No. 113-79, 128 Stat. 651.

[70] H.R. Rep. 113-333, at 531 (2014); *see also id.* at 532–33.

[71] EPA, NMFS, & FWS, Interim Report to Congress on Endangered Species Act Implementation in Pesticide Evaluation Programs (Nov. 2014), https://www.epa.gov/sites/production/files/2015-07/documents/esareporttocongress.pdf.

[72] *Id.* at 22.

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In fact, however, as EPA is well aware,[73] efforts to date to implement the interim processes have demonstrated that many of the scientific strategies it embodies are unworkable. Initially, the schedule called for EPA to complete and submit the BEs for products containing the three OP active ingredients by March 2016.[74]

When EPA opened the draft BEs for public comment in April 2016, they were subject to enormous criticism from a wide range of interests.[75] That criticism included that the drafts were released after the March 2016 deadline for the *final* BEs. EPA ultimately "finalized" the BEs without responding to most of the substantive criticisms it had received, incorrectly asserting that it did not have time to do so because of pending court deadlines.[76] NMFS nonetheless prepared the BiOp now out for comment without recognizing those failures and while making many other errors.[77] As explained more fully in the attachments, the BiOp is thus largely worthless as a decision-making tool.

But this experience does serve one important function: it demonstrates that a wholesale revisitation of the Interim Approaches is required. And the Administration has created a vehicle for that reconsideration: The Working Group established by January 2018 Memorandum of Agreement between the agencies.[78]

The appropriate response to both these comments and others being filed with EPA has three elements. First, NMFS should withdraw the BiOp, and, even if NMFS does not, EPA should set it aside. Second, both EPA and NMFS should review carefully and develop adjustments to the FIFRA/ESA integration process, as suggested by the comments on the BiOp. Third, the interim process should be replaced with a process that will be both scientifically sound and consistent with the requirements of both FIFRA (especially section 3 and 33) and ESA section 7.

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[73] Letter from Rick Keigwin, Jr., Director, Office of Pesticide Programs, USEPA, to Donna Wieting, Director, Office of Protected Resources, NMFS (Feb. 21, 2018), https://www.regulations.gov/document?D=EPA-HQ-OPP-2018-0141-0004.

[74] Decl. of Samuel D. Rauch in Supp. of Mot. to Amend Dkt. 50 ¶ 19, *Nw. Ctr. For Alternatives to Pesticides v. NMFS*, No. 07-cv-1791 (W.D. Wash. Nov. 9, 2017), ECF 51-2.

[75] *See* Malathion, Diazinon, and Chlorpyrifos registration review dockets, *supra* note 2.

[76] EPA Response to Comments, https://www3.epa.gov/pesticides/nas/final/response-to-comments.pdf.

[77] Intrinsik General Comments at 4–8.

[78] EPA, Dep't of Interior, & Dep't of Commerce, Memorandum of Agreement on Establishment of an Interagency Working Group to Coordinate Endangered Species Act Consultations for Pesticide Registrations and Registration Review (Jan. 31, 2018).

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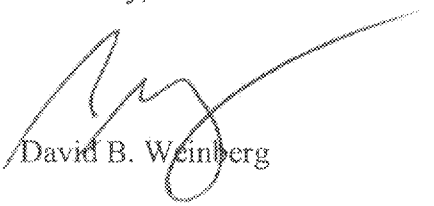
Thank you for your consideration of these comments and their attachments.

Sincerely,



David B. Weinberg

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Enclosures